JUN 2 1 2006

K061590
p 1/3

Siemens Medical Solutions Health Services Corporation
Traditional 510(k) Premarket Submission
SMDIE Device Interfacing System

SECTION 5 – 510(k) SUMMARY

Submission Correspondent: Emergo Group, Inc.
Address: 2454 McMullen Booth Road
Suite 427
Clearwater, FL 33759
Phone: (727) 797-4727
Fax: (727) 797-4757
E Mail: igordon@emergogroup.com

Contact: Mr. Ian Gordon
Senior Vice President

Submission Sponsor: Siemens Medical Solutions Health Services Corporation
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: May 19, 2006

Trade Name: SMDIE Device Interfacing System

Common Name: Physiological device data retriever and translator

Classification: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Regulation #: 870.2300, Class II
Product Code: MWI

Description: The SMDIE Device Interfacing System Software is intended for use with standalone physiological monitor and Scale-Tronix 5002 scales to transfer data from the physiological monitor and scale to external devices via Health Level Seven data exchange protocols for vitals results and patient information.[1]

[1] "Health Level Seven is one of several American National Standards Institute (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data." Source: http://www.hl7.org.

Siemens Medical Solutions Health Services Corporation
Traditional 510(k) Premarket Submission
SMDIE Device Interfacing System

External physiological monitors and scales are connected to the SMDIE Device Interfacing System via a standard serial port connector.

Serial interfaces between physiological monitors and the SMDIE allow patient weight, non-invasive blood pressure, blood oxygenation level, and temperature to be communicated to the Device Connectivity & User Interface Component.

List of Classification names and numbers of externally connected devices are as follows:

- Cardiac Monitor – 870.2300
- Clinical Electronic Thermometer – 880.2910
- Oximeter – 870.2700
- Non-Invasive Blood Pressure Measurement System -- 870.1130
- Breathing Frequency Monitor – 868.2375

Intended Use: The SMDIE Device Interfacing System is indicated for data transfer between standalone physiological monitors that collect noninvasive blood pressure, temperature, and blood oxygenation level through external cuffs and thermometers to external clinical information systems. The SMDIE is also indicated for patient weight transfer between Scale-Tronix 5002 class physician office scales. The SMDIE Device Interfacing System is not intended for continuous vital sign monitoring purposes.
For Prescription Use Only.

Predicate Devices:
The SMDIE Device Interfacing System substantially equivalent to the following predicate devices.

M2367A Device Link System by Agilent Technologies, Inc.
510(k) #: K012094
Decision: Substantially Equivalent (SE)

Unity Network ID by General Electric Medical Systems Information Technology
510(k) #: K021454
Decision: Substantially Equivalent (SE)

DataCaptor by Capsule Technologie
510(k) #: K032142
Decision: Substantially Equivalent (SE)

Integriti Patient Monitor by Alliance Instruments
510(k) #: K980688
Decision: Substantially Equivalent (SE)

Centra View Device Link System by ICU Data Systems, Inc.
510(k) #: K033283
Decision: Substantially Equivalent (SE)

Safety and Effectiveness and Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The minor differences between the SMDIE Device Interfacing System and the predicate devices cited do not raise any additional questions regarding safety and effectiveness. Software Testing was performed on the SMDIE Device Interfacing System and was determined to be acceptable.

The device, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2006

Siemens Medical Solutions Health Services Corporation.
c/o Mr. Daniel W. Lehtonen
Responsible Third party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K061590
Trade Name: SMDIE Device Interfacing System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm).
Regulatory Class: II (two)
Product Code: MWI
Dated: June 7, 2006
Received: June 8, 2006

Dear Mr. Daniel W. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061590

INDICATIONS FOR USE

510(k) Number (if known): ______________________

Device Name: SMDIE Device Interfacing System

Indications for Use:

The SMDIE Device Interfacing System is indicated for data transfer between standalone physiological monitors that collect noninvasive blood pressure, temperature, and blood oxygenation level through external cuffs and thermometers to external clinical information systems. The SMDIE is also indicated for patient weight transfer between Scale-Tronix 5002 class physician office scales. The SMDIE Device Interfacing System is not intended for continuous vital sign monitoring purposes.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061590